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PAUL J. COTE, JR.
COMMISSIONER

TO: Commissioner Cote and Members of the Public Health Council

FROM: Paul Dreyer, Associate Commissioner, Center for Quality Assurance and Control

SUBJECT: Request for Final Promulgation of Amendments to 105 CMR 150.000 et seq. Regarding the Provision of Automated External Defibrillators

DATE: May 24, 2005 (Issued May 17, 2005)

Background

In the United States, approximately 250,000 people per year die from sudden cardiac arrest outside a hospital setting. Most of these deaths are due to sudden abnormal heart rhythms (arrhythmias), of which ventricular fibrillation is the most common form. Defibrillation is the only known therapy for ventricular fibrillation, and the chances of survival of cardiac arrest decrease by approximately ten percent for every minute that defibrillation is delayed. Current technology provides automated external defibrillators (AEDs) that are safe, low maintenance, require very little training to operate, and cost as little as $1000. The American Heart Association recommends AEDs be installed in settings where they are likely to be used once for each 50,000 person days. This would include most nursing facilities, when staff and visitors are counted.

The purpose of this memorandum is to request final promulgation of amendments to the Long Term Care Facility Licensure Regulations (105 CMR 150.000) which would require each nursing facility to acquire at least one automated external defibrillator, and contract with a physician (who may be the current facility medical director) to oversee the development of policies and procedures regarding the training of staff in the use of an AED, the maintenance and testing of the AED equipment, and performance review of AED activity in the facility.

A public hearing on these amendments was held on February 18, 2005, and comments were accepted through February 23. Massachusetts Aging Services Association, Inc. (MassAging) presented testimony at the hearing. Written comments were also submitted by The Loomis Communities, the Massachusetts Extended Care Federation (MECF), the American Heart Association (AHA), and the Professional Fire Fighters of Massachusetts. The issues raised in the comments are summarized below.

Comments and Responses

1. **Potential liability for facilities**

MassAging and MECF offered concerns that the existence of an AED on the premises might lead to unrealistic expectations regarding outcomes of residents who are treated with an AED because, unlike in

an airport, mall or health club where an AED may be installed, nurses are present. Concerns about the escalating costs of liability insurance for long term care facility providers were also mentioned.

Response: Along with training staff, facilities would need to inform and educate residents and family members about the availability of AEDs in the facility, the facility policy regarding AED use and the impact, if any, on other facility policies (e.g., DNR policies). MGL C 112, section 12V offers liability protection to laypersons who are trained in the use of defibrillators. Health care workers who use an AED in the course of their professional duties are not covered by this liability protection; professional standards of practice would apply.

According to the National Center for Early Defibrillation, few lawsuits have arisen directly involving AEDs. Most suits have been filed against organizations (e.g., an airline, fitness center or theme park) that did not have AEDs. With that in mind, it is possible that there is potential increased liability for not having an AED on site.

Although the Department is aware of liability insurance cost concerns, it has no control over them.

2. **Cost of equipment purchase and training of staff without additional, expedited reimbursement**

MassAging, MECF and The Loomis Communities commented that without additional immediate reimbursement for the cost of equipment ($1-2000/machine), maintenance and staff training, facilities should not be required to incur this additional expense. MECF estimated that under the current reimbursement system the earliest facilities would receive some reimbursement for the costs associated with implementing these regulations would be 2007. In addition, at least half of the facilities would not have any of the costs recognized under the 'median pricing system'.

Response: The Division of Health Care Finance and Policy's regulations regarding Medicaid reimbursement for nursing facilities do not include a provision that would allow a facility to petition for an adjustment to a facility's daily rate. These costs would be reimbursed under the current system.

3. **Outcomes of using AEDs in the long term care population**

Comments included statements that AEDs are not sufficiently effective for the elderly population to justify their use.

Response: The Department, after discussion with medical experts, is unaware of evidence to support the assertion that AEDs are not effective in the elderly population.

4. **Do Not Resuscitate (DNR) Orders**

The MECF and MassAging commented that many residents have Do Not Resuscitate (DNR) Orders. The Loomis Communities commented that over 90% of their residents have DNR orders and would not be defibrillated. In addition, they added that the time it takes to confirm that a resident does not have a DNR order will delay the time to treatment, which according to all the literature is extremely time sensitive, with the best outcomes for those who receive a shock within the first few minutes of a witnessed collapse due to cardiac arrest.

Response: Residents with DNR orders will be unaffected by the availability of AEDs in a facility. For residents without DNR orders, visitors and staff who might experience sudden cardiac arrest, while it is true that the sooner the shock is received the higher the probability of positive outcome, a positive outcome may still be obtained for up to 10 minutes from cardiac arrest.

5. **Proposed applicability to post-acute units only**

MassAging commented that most of the facilities that have purchased AEDs have larger post-acute units. They suggested that perhaps the requirement should only apply to facilities with primarily post-acute residents.

Response: Although the Department understands that many nursing facility residents are recuperating from a hospital stay, the Department does not recognize through the licensure regulations a separate licensure category for residents that are identified by nursing facilities as post-acute care. Any Medicare-certified nursing facility bed could be a post-acute bed. In addition, staff and visitors may also benefit from the availability of an AED on site. Therefore the Department continues to recommend that the requirement apply to all nursing facilities.

6. **Regulatory change should be accompanied by a DPH directive**

MECF recommended that any regulatory change regarding AEDs should be accompanied by a DPH directive identifying the risks associated with the equipment and permitting a facility to inform its residents of the risks.

Response: As with any new long term care facility licensure regulation, the Department would issue a letter to all long term care facility administrators informing them of a new requirement. The Department would include in that letter American Heart Association referral information. Facilities do not need the Department's permission to inform residents of any risks associated with the use of an AED. In fact, the Department would expect that as part of an informed consent process and educational materials, such risks would be explained.

7. **No other state requires AEDs in nursing facilities**

MECF commented that it was unaware of any other state that requires AEDs in nursing facilities.

Response: In July, 2004, New Jersey passed legislation requiring each nursing home to acquire at least one defibrillator. Since the issuance of the proposed Massachusetts amendments, in February, 2005, the New York City Council passed legislation requiring many public places, including nursing homes and senior centers, to have AEDs. The state of Maine has legislation pending this session to require long term care facilities, residential care facilities, and assisted housing and assisted living programs to have an AED on each floor of the facility. Maryland has legislation pending to require AEDs in nursing homes and assisted living facilities.

8. **Clarification that the requirement applies only to nursing facilities, not residential care facilities/rest homes**

Although it was the intent for this amendment to apply to nursing homes and language to that effect was included in the purpose and background of the informational briefing material presented to the Public Health Council in December 2004, the regulatory language (the actual amendment) as originally proposed does not specify that it would apply only to nursing homes. The Division has added language to clarify this intent.

DPH will include language to require AEDs in residential care facilities when the separate Residential Care Facilities Licensure Regulations are released for public hearing and comment.

9. **Clarification of language regarding a medical director for AED**

As originally proposed, the amendment required the facility medical director to be the AED medical director for the facility. Although many long term care facilities have advisory physicians or medical directors, there is no state licensure regulation that specifically requires a 'medical director'. (Under the regulations, an "Advisory Physician" advises on the conduct of medical and medically related services in

the facility. The federal certification standards require a medical director.) Therefore, the amendment language has been revised to require for the purposes of this regulation that the facility contract with or employ a physician who shall be the AED medical director for the facility. This could be the facility's current Advisory Physician.

10. **Support of the proposed amendments**

The Professional Fire Fighters of Massachusetts and the American Heart Association offered comments in support of the proposed amendments.

11. **Change in the implementation deadline**

The Department has changed the proposed implementation deadline from September 30, 2005 to November 30, 2005, to give facilities more time to implement the proposed amendments.

Recommendation

The Division recommends the final promulgation of the amendments, as revised in Attachment A subsequent to the receipt of public comments, in order to provide this life saving technology to residents, staff and visitors to nursing facilities. This recommendation is consistent with the recommendations of the American Heart Association, which advocates for the placement of AEDs in public and private places where large numbers of people gather and/or where people who are at high risk for sudden cardiac arrest live.